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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,404	03/04/2002	John N. Feder	8907-098-999	9646

7590

08/12/2003

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/12/2003

67

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/092,404

Applicant(s)

FEDER ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 7. 6) ☐ Other: _____

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DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a divisional of U.S. Application Serial Number 09/094,964, which is a continuation-in-part of U.S. Application Serial Number 08/876,010.

Claims 1-6 have been canceled previously.

Claims 7-9 were previously added and are currently pending.

Election/Restrictions

1. Applicant's election without traverse of the species disclosed as SEQ ID NO: 3 as the sequence to be examined in Paper No. 8, filed May 8, 2003, is acknowledged.

Accordingly, claim 9 reads upon the elected species. However, upon further review, the **species election requirement is hereby withdrawn and claims 7-9 are the subject of examination in the present Office Action.**

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is drawn to a composition comprising an HFE polypeptide having the amino acid sequence of SEQ ID NO: 1 and a full-length, wild-type human β_2m . SEQ ID NO: 1 represents a polypeptide fragment of the human HFE protein. Applicant is reminded that the term "having" is regarded as open language, meaning that a recitation of a polypeptide having a recited amino acid sequence is inclusive of polypeptides/proteins comprising the recited sequence in addition to additional amino acid residues attached to either end. Accordingly, the present recitation reads upon a composition comprising human HFE protein and full-length, wild-type human β_2m . Further, as said HFE protein and

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wild-type human β_2m are naturally produced and present in the human body, the claim reads upon a human being, which is a product of nature and therefore unpatentable.

It is suggested that Applicant amend the claim to recite --an isolated composition-- or to recite --HFE polypeptide consisting of the amino acid sequence--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by either U.S. Patent No. 6,025,130 to Thomas et al (A on form PTO-892) or U.S. Patent No. 6,140,305 to Thomas et al (B on form PTO-892).

The '130 and '305 patents each disclose wild type and mutant forms of the HH protein, which is the same protein disclosed instantly as HFE. For the purpose of the present discussion, the elements will be addressed as they appear in the '305 patent. Applicant is reminded that the term "having" is interpreted as an open term consistent with the recitation of "comprising" and the recitation of "having" in these claims therefore opens the claims up to include unrecited elements including the additional amino acid residues of the full-length protein. The '305 patent teaches the HH gene product of SEQ ID NO: 2 as a 348 amino acid residue polypeptide having instant SEQ ID NO: 1 as amino acid residues 1-276 [instant claim 7]. The '305 patent also teaches the mutant HH gene product of SEQ ID NO: 6 as a 348 amino acid residue polypeptide having instant SEQ ID NO: 2 as amino acid residues 23-298 [instant claim 8].

The '305 patent further teaches that the HH gene product possesses significant homology to HLA Class I molecules which are known to interact with β_2 microglobulin and that β_2 microglobulin knock-out mice developed symptoms of iron overload disease (column 14, lines 28-54 in particular) which is a

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phenocopy of human hemochromatosis (column 24, lines 4-13 in particular). The '305 patent further teaches that a mutation in the β_2 microglobulin binding domain of the HH gene product predicted to ablate binding of the gene product to β_2 microglobulin was common to the majority of patients with human hemochromatosis (column 14, lines 28-54 in particular). The '305 patent teaches that when this binding is lost, the protein no longer is located on the cell-surface (column 24, lines 4-13 in particular).

The '305 patent also teaches that the HH gene product can be purified by conventional affinity chromatography techniques based on its homology with MHC Class I molecules. The '305 patent teaches immobilization of β_2 microglobulin on an inert matrix for purification of the HH gene product (column 24, lines 15-48 in particular). Accordingly, the purification procedure results in the production of a composition comprising an HH gene product, or HFE polypeptide, having SEQ ID NO: 1 or 2 and a full length, wild type human β_2 microglobulin. The prior art anticipates the claimed invention.

Information Disclosure Statement

4. References AQ, AR, AS and AZ on Applicant's form PTO-1449 filed July 23, 2002 have been lined through because they are duplicate citations of AN, AO, AP and AE, respectively.

Conclusion

4. Claim 9 is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
August 11, 2003

PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
TECH CENTER 1600
8/11/03